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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/866,354	05/30/97	FOX G.	A-401B

HM21/0306

U S PATENT OPERATIONS DRC
M S 10 1 B
AMGEN INC
1840 DE HAVILLAND DRIVE AMGEN CENTER
THOUSAND OAKS CA 91320-1789

EXAMINER	
HAYES, R	

ART UNIT	PAPER NUMBER
1645	3

DATE MAILED: 03/06/98

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
08/866354	Fox et al.
Examiner	**Group Art Unit**
HAYES	1645

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Response

A SHORTENED STATUTORY PERIOD FOR RESPONSE IS SET TO EXPIRE 30 days ~~MONTH(S)~~ FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a response be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for response specified above is less than thirty (30) days, a response within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for response is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to respond within the set or extended period for response will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

☒ Claim(s) 1-69 is/are pending in the application.

Of the above claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claim(s) 1-69 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received: _____.

Attachment(s)

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of References Cited, PTO-892

☐ Notice of Informal Patent Application, PTO-152

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Other _____

Office Action Summary

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-12, 35-36 & 51-52, drawn to GDNF receptor proteins, and compositions thereof (i.e., as it relates to claim 36), classified in class 514, subclass 12.

II. Claims 13-26, 28-34, 53-58 & 60, drawn to nucleic acids encoding GDNF receptor proteins, vectors, host cells, and methods of producing this receptor protein, classified in class 435, subclass 69.1.

III. Claims 37-40 & 61, drawn to methods of treating neuronal cell populations/neural disease states by administering a GDNF receptor protein, classified in Class 514, subclass 2.

IV. Claims 41-45 & 62-63, drawn to antibodies of the GDNF receptor protein, and hybridoma cells producing such, classified in Class 435, subclass 346.

V. Claims 27, 46-48, 59 & 64, drawn to a device for treating nerve damage that comprises encapsulated cells on a semipermeable membrane, classified in Class 424, subclass 93.1.

VI. Claims 49-50 & 65-66, drawn to an assay device and methods for detecting GDNF receptor in a test sample, classified in Class 435, subclass 7.1+.

VII. Claims 67-69, drawn to methods for determining whether a ligand activates a receptor tyrosine kinase in a test sample comprising a GDNF receptor, classified in Class 435, subclass 7.21.

2. The inventions are distinct, each from the other because of the following reasons:

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different products, restriction is deemed to be proper, because these products appear to constitute patentably distinct inventions for the following reasons:

Groups I-II & IV-VI are directed to products that are physically and functionally distinct; involving proteins, nucleic acids and antibodies. All of these products can be prepared by different processes, such as though chemical synthesis or isolation from natural sources using various isolation/purification procedures. For example, the proteins of Group I and antibodies of Group IV are fundamentally different molecules than the nucleic acid molecules of Group II, which in turn can be used to clone proteins, detect cells that express the protein, or used as therapeutic agents in gene therapy. Although the antibodies of Group IV can be used in isolating the proteins of Group I, the antibodies of Group IV can be generated by immunizing animals with a small synthetic portion of the full length protein, and can be used diagnostically in other ways, such as in affinity chromatography or in immunoassays, or as therapeutic agents themselves. The proteins of Group I can be utilized in making the antibodies of Group IV, but not vice versa.

Although the device of Group V and the products of Group II require cells that express the protein, no semipermeable membrane is required for the host cells of Group II, as required for Group V. Additionally, neither the proteins of Group I nor the antibodies of Group III require the vectors and host cells of Group II, and vice versa. Finally, none of the products of Groups I-II & IV-V require the solid phase, test samples, or detectable reaction products of the assay device of Group VI, and vice versa. It is pointed out that there is a proper distinction between these groups, since each product is not required in order for the other to exist. Thereby, these groups are distinct and separable for the reasons stated.

Groups I and III, VI-VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the proteins of Group I can be used in other materially different methods, such as in affinity chromatography for isolating GDNF analogs. In contrast, the method of treating patients with GDNF receptor protein in Group III requires cells in a patient to treat, while the assay method of Groups VI-VII requires either a solid phase, test samples/ligand complexes, or detectable reaction products; none of which are required in the products of Group I.

It is noted that the methods of Groups III & VI-VII do not require the products of Groups II & IV, and vice versa; nor do they require the encapsulated cells of Group V.

Although there are no provisions under the section for "Relation of Inventions" in M.P.E.P. 806.05 for inventive groups that are directed to different methods; restriction is deemed proper because these methods appear to constitute patently distinct inventions for the following reason:

Groups III & VI-VII are directed to methods of treating a patient, or detecting the presence of a protein. Each of these methods require physically and functionally distinct elements. For example, the methods for detecting the presence of the GDNF receptor protein in Group VI is distinguished from the treatment methods of Group III, in that the assay method of Group VI requires labeling reagents, solid phases, and test samples, unlike the methods of treating neurons/neural disease states of Group III. Likewise, the methods for determining whether a GDNF receptor protein/ligand complex will activate a tyrosine kinase in Group VII is distinguished from the treatment methods of Group III, in that the assay method of Group VII requires labeling reagents for detecting phosphorylation, test ligands, and tyrosine kinase molecules, unlike the methods of treating neurons/neural disease states of Group III. Further, the methods of Group III require patients to treat, unlike the assay methods of Groups VI-VII. Lastly, the assay methods of Group VI require solid supports and different detection reagents than the assay methods of Group VII, which themselves require tyrosine kinase molecules, unlike the methods of Group VI. These inventions are, therefore, patentably distinct, since one is not required for the other.

3. Because these inventions are distinct for the reasons given above, they have acquired a separate status in the art as shown by their different classification, and the non-coextensiveness of the search and examination for each group would constitute an undue burden on the examiner to search and consider all the separable groups with their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(I).

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (703) 305-3132. The examiner can normally be reached on Monday through Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell, can be reached on (703) 308-4310. The fax phone number for this Group is (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

RCH

Robert C. Hayes, Ph.D.
March 2, 1998

ANTHONY C. CAPUTA
PRIMARY EXAMINER
GROUP 1800